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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,105	07/15/2002	Terry Roemer	110182-015-999	5750

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EXAMINER	
BURKHART, MICHAEL D	
ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/018,105	ROEMER ET AL.	
	Examiner	Art Unit	
	Michael D. Burkhart	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 24-27* is/are pending in the application.

4a) Of the above claim(s) *4,6-9,12-20 and 24-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3 and 10* is/are rejected.

7)☒ Claim(s) *1, 5, and 11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *7/15/2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group II, claims 1-3, 5, and 10-11, in the reply filed on 3/28/2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 4, 6-9, 12-20, and 24-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/28/2005.

Priority

This application, filed 7/15/2002, is a 371 of PCT/CA00/00533, filed 5/5/2000, which claims benefit of 60/132,878, filed 5/5/1999. However, 38 months had elapsed from the claimed priority date (5/5/1999) until the filing date of the National Stage Application (7/15/2002). Therefore, the priority claimed to the 60/132,878 application does not meet the 30-month deadline stated in PCT Article 22. The instant invention is granted a priority date of 5/5/2000.

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Sequence Rules

Figures 1-3 contain sequences not identified by a SEQ ID number in the figures or in the Brief Description of the Drawings. These details are requirements of the Sequence Rules (MPEP 2400 §1.821-1.825) and must be corrected. Any response which does not include compliance with the Sequence Rules will be considered non-responsive.

Claim Objections

Claims 1-3 and 10 are objected to for reciting non-elected subject matter (i.e. any SEQ ID NO other than SEQ ID NOs 3 or 4) or non-elected claims.

Claim 11 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites a nucleic acid sequence that hybridizes over "substantially" the entire length of a nucleic acid encoding SEQ ID NO 4. It cannot be determined what constitutes

"substantially" the entire length of the claimed sequence. For example, would hybridizing to one-half the sequence be considered "substantial", or does it require hybridization to three-quarters of the sequence? For this reason, one of skill in the art could not determine what constitutes infringement of the claim, and therefore the metes and bounds of the claimed subject matter are unclear.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2 and 3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claim a nucleic acid comprising: a sequence that hybridizes over substantially the entire length of any nucleic acid encoding SEQ ID NO 4; or, a nucleic acid sequence having at least 70% identity over at least one sequence window of 48 nucleotides with a nucleotide sequence encoding the amino acid sequence of SEQ ID NO 4. Applicants disclose the nucleic acid sequence of SEQ ID NO 3 and that it encodes the amino acid sequence of SEQ ID NO 4, the CaALR1 protein of *C. albicans*. The claims read on a very large genus of potential nucleic acids segments that hybridize to SEQ ID NO 3, for example, or that have only 70% identity to any 48-residue sequence selected from SEQ ID NO 3, which is 3,525 residues in length. The written description requirement for a genus may be satisfied by sufficient description of a

representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between structure and function, or by a combination of such identifying characteristics, sufficient to show that applicant was in possession of the claimed invention.

In the instant case, applicants only disclose SEQ ID NO 3, a nucleic acid that encodes CaALR1, the amino acid specified in SEQ ID NO 4. The prior art discloses the *S. cerevisiae* proteins ALR1 and ALR2 that have some homology to CaALR1 (see Fig. 2 of the specification). Neither applicants nor the prior art disclose functional domains of CaALR1. Furthermore, applicants state (page 35, lines 24-31) that " *CaALR1* shares only limited homology, however, to two highly homologous regions common to *ALR1* and *ALR2*; neither the N-terminal 250 amino acids of *CaALR1* nor its last 50 amino acids C-terminal [to] the hydrophobic domain share strong similarity to *ALR1* or *ALR2*. In addition, *CaALR1* possesses two unique sequence extensions within the CorA homology region (one 38 amino acids in length, the other, 16 amino acids long) not found in either *ALR1* or *ALR2*." If the functional domains of the claimed sequence are unclear, how can there be a basis for one skilled in the art to envision embodiments other than the disclosed SEQ ID NO 3? That is to say, how could the skilled artisan envision the claimed hybridizing segments or introduce the claimed sequence variation and still retain a CaALR1 protein? There simply is no structural/functional basis provided to envision other embodiments. Applicants claim nucleic acids segments that hybridize to the disclosed sequence and nucleic acids with 70% homology to the disclosed sequence, over a short 48-nucleotide portion, by function only, without a correlation between structure and function. The prior art does not

compensate for the lack of description of functional domains. The lack of disclosure and broad genus regarding the claimed nucleic acids would require the skilled artisan to conclude that the example presented by the applicants are not sufficient to describe the claimed genus.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 3 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Weinstock et al (US Patent 6,747,137, filing date 2/12/1999, effective filing date 8/13/1998). The claims recite an isolated nucleic acid molecule that may: have at least 70% identity over at least one sequence window of 48 nucleotides with a nucleotide encoding SEQ ID NO 4; or consist of 10 to 50 nucleotides that hybridizes to at least 10 consecutive nucleotides of SEQ ID NO 3, or a complementary strand thereof.

Weinstock et al disclose SEQ ID No 6328, which, as one example, has an identical nucleotide sequence over residues 405-464 (of the instantly claimed SEQ ID NO 3 (see sequence alignment for result no. 1, Issued Patents database, included in the search results). Therefore, Weinstock teach a nucleic acid with at least 70% (100% in this case) identity to any 48-nucleotide sequence chosen from the above alignment of 59 residues. Weinstock list as

preferred embodiments nucleotides of from about 8 to 20 nucleotides corresponding to any of SEQ ID NOs 1-14103 (column 8, lines 6-10). Any nucleotide 10-50 bases in length selected from the portion of SEQ ID NO 6328 indicated above would hybridize to the corresponding portion of SEQ ID NO 3 because of the 100% sequence match.

Conclusion

Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael D. Burkhart
Examiner
Art Unit 1636

CELIAN QIAN
PATENT EXAMINER